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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,973	06/04/2001	Gustav Gaudernack	1702.401500	8016

5514 7590 07/08/2003

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	17

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/674,973	Gaudernack et al.
Examiner	**Art Unit**
Michael Borin	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 4/30/03

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 35-73 is/are pending in the application.

4a) Of the above, claim(s) 36, 38-49, and 52-73 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 35, 37, 50, and 51 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 35-73 are pending.

2. Supplemental Response to restriction requirement filed 4/30/03 is acknowledged. Applicant elected, Group I.2, claim 37, with claims 35,50, 51 also reading on the elected SEQ ID No. 17.

In the initial response to restriction requirement filed 04/03/2003 applicant elected Group I and requested rejoinder of Groups I and IV. Applicants refer to MPEP addressing restriction requirements; however, as this a national stage of a pct application, lack of unity rules rather than US practice restriction rules apply in this case. As was stated in the previous Office action, the inventions do not relate to a single general inventive concept under PCT Rule 13.1 because Group I, which is the technical feature that links Groups I-XI, is not the contribution over the prior art as it is suggested by references cited in the International Search report issued in the preceding PCT case, as well as by plurality of references teaching peptide fragments. See, further, an art rejection below. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2. In addition, had it been under US restriction practice, distinctness between product and method of use can be one way, and, in the instant case, the product (SEQ

ID No. 17) can be used in other methods, e.g., for cancer diagnosis and detection (as described in WO 96/31605 used in the art rejection below).

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 36,38-49,52-73 are withdrawn from further consideration by the examiner as being drawn to a non-elected groups. Cancellation of claims 36,38-49,52-73, and amendment of claims 35,37,50,51 to read on elected invention are requested.

Applicant also requested examination of SEQ ID No. 428 together with SEQ ID No. 17. Examiner agrees and included SEQ ID No. 428 in consideration.

Claims 35,37,50,51 are examined to the extent they read on the elected peptide SEQ ID Nos. 17 and 428.

Information Disclosure Statement

3. Applicants' Information Disclosure Statement filed 2/8/01 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Abstract

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Sequence Listing

5. The Sequence Listing was approved by STIC for matters of form.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 35,37,50,51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claim 37: As the claim is viewed to the extent it reads on the elected SEQ ID 17, it is not clear whether the peptide is a fragment of a protein produced by TGF gene or BAX gene.

B. Claim 50: Similarly, As the claim is viewed to the extent it reads on the elected SEQ ID 17, which is 23 residue long, it is not clear how the peptide can be 8-25 residues long as recited in the claim.

C. Claim 51: the claim, as reciting products of claims 36,38-49, reads, in part, on subject matter now withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn to pharmaceutical composition comprising peptide SEQ ID No. 17 or 428. The specification, while providing examples of *in vitro* use of the peptides (pages 46-53), does not demonstrate their *in vivo* use. Although the specification mentions, hypothetically, that peptide SEQ ID No. 17 being a tumor specific antigen may be used in a vaccine (p. 53, line 29), there is no showing of such use. For the claim to a pharmaceutical composition to be enabled, the specification must teach how to make the claimed composition without undue experimentation and must teach how to use the composition for at least one pharmaceutical use without undue experimentation. There is no showing that antibodies produced in response to

the claimed peptides will be able of protecting the individual from contracting a disease, i.e., vaccination. The specification must teach how to use the substance, without undue experimentation, for the prevention, alleviation, treatment, or cure a disease in the animal to which the substance is administered.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 35,37,50 are rejected under 35 U.S.C. 102(b) as anticipated by WO 96/31605.

The reference teaches inactivated mutant TGFβ receptors RII which can be used for generating antibodies specifically immunoreactive with mutant RII. See pages 2-3. In particular, the reference teaches truncated polypeptide comprising non-mutant part, and, at C-terminal, a sequence of SEQ ID No. 3 (see paragraph bridging pages 29-30):

SLVRLSSCVPVALMSAMTTSSSQKNITPALTCC

wherein the highlighted part of the sequence is the instantly claimed SEQ ID No. 17, and underlined part of SEQ ID No. 17 is its fragment, SEQ ID No. 428.
As such, the referenced protein reads on the instantly claimed peptide having 0-10 residues of a normal part of the sequence connected to a mutant part, which, in this case, is SEQ ID Nos. 17 or 428.

It is Examiner's position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the reference cited above.

Prior art made of record

9. References D1,D2, D3, D5 D11 in the International Search report discuss obviousness of the general approach of producing small peptides having, in part, novel sequences created by a mutation in gene.

Further, International Search report refers to reference D7 therein as showing that all peptides of this invention are based on the known frame shift in the wild type RII RNA repeat sequence of 10 adenines at nucleotides 709-718.

Conclusion.

10. No claims are allowed

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 7, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER